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| 10/072,697      | 02/07/2002  | Jeffrey M. Wendlandt | 1001.1440101        | 2520             |

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EXAMINER

PANTUCK, BRADFORD C

ART UNIT PAPER NUMBER

3731

DATE MAILED: 07/31/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

NK

# Office Action Summary

Application No.

10/072,697

Applicant(s)

WENDLANDT, JEFFREY M.

Examiner

Bradford C Pantuck

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-13, 15, 16, and 18-21 is/are rejected.
- 7) ☒ Claim(s) 10, 14 and 17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 & 4. 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 15 recites the limitation "the apertures" in line 3. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-6, 11, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Pub. No. US 2003/0040761 A1 to Pugsley et al. Regarding Claim 1, Pugsley discloses a surgical clip, as shown in Figure 2, with two pieces. The first piece (13) has a first base (21) and a first projection (23) extending from the first base [see Fig. 2]. The second piece (15) has a second base (33-1 bottom portion) and a second projection (33-1 top portion and 41-1) extending from the base [see Attachments #1

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and #2]. The second projection includes multiple surfaces (interior), which define a reservoir. The surfaces include a surface towards the bottom of the cylindrical inner surface of the projection and side portions. The two pieces are detachably connectable when the first projection (23) passes into the reservoir {see Fig.3; paragraph [0037]}. That is, because Pugsley's second projection (33-1 top portion and 41-1) is coated with a bioabsorbable material {see paragraph [0037]}, when the clip (or part of the clip) degrades, the two pieces will disengage.

3. Regarding Claim 2, Pugsley's first base (21) is substantially circular. That is, the whole member 21 is *cylindrical*, but any cross section of it (*which could be called the first base*) is circular [see Figures 2 and 3].
4. Regarding Claim 3, Pugsley's second base (33-1 bottom portion) is substantially circular [see Figures 2 and 3].
5. Regarding Claim 4, Pugsley's surgical clip has multiple surfaces that define a generally cylindrical surface of the reservoir (33-1 inside surfaces) [see Fig. 3].
6. Regarding Claim 5, the first projection (23) of Pugsley's surgical clip extends perpendicular relative to the first base (21) [see Figures 2 and 3].
7. Regarding Claim 6, the second projection (33-1 top portion and 41-1) of Pugsley's surgical clip extends perpendicular relative to the second base (33-1 bottom portion) [see Figures 2 and 3].
8. Regarding Claim 11, Pugsley's surgical clip has a second projection with an aperture (39-1) {see paragraph [0035]}, which is capable of allowing the flow of a

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therapeutic agent out of the reservoir after the first piece (13) and second piece (15) are detachably connected [Fig. 2].

9. Regarding Claim 12, as discussed in paragraph [0011] the first piece (13) of Pugsley's fastener may be made out of a biodegradable material and the second piece (15) is made out of a second biodegradable material having a second degradation rate.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-9, 13, 15, 16, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,016,369 to Parry. Regarding Claim 1, Parry discloses a clip, as shown in Figure 2, with two pieces. The first piece (2) has a first base (4) and a first projection (5) extending from the first base [see Fig. 1]. The second piece (3) has a second base (9) and a second projection (10) extending from the base [see Fig. 1]. The second projection includes multiple surfaces (interior), which define a reservoir (12). The two pieces are detachably connectable when the first projection (5) passes into the reservoir (12) [see Fig. 1; Column 2, lines 50-68].
11. Regarding Claim 2, Parry's first base (4) is a circular "disk" [Column 2, lines 55-56].
12. Regarding Claim 3, Parry's second base (9) is a circular "disk" [Column 2, lines 63-64].
13. Regarding Claim 4, Parry's clip has multiple surfaces that define a generally cylindrical surface of the reservoir (12) [see Fig. 1].

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14. Regarding Claim 5, the first projection (5) of Parry's surgical clip extends perpendicular relative to the first base (4) [see Fig. 1].
15. Regarding Claim 6, the second projection (10) of Parry's surgical clip extends perpendicular relative to the second base (9) [see Fig. 2].
16. Regarding Claims 7 and 8, the top surface of Parry's multiple surfaces is a puncturable material (14). The first projection (5) is adapted to pierce through the tops surface (14) [Column 3, lines 21-24; Fig. 2].
17. Regarding Claim 9, the reservoir of Parry's clip contains a therapeutic agent—i.e. a sterilizing substance or other drug [Column 3, lines 1-3].
18. Regarding Claim 13, Parry discloses the invention, as claimed, and as explained above. Further, the second projection of Parry's clip has an aperture, at the point where the tip of the first projecting portion (5) broke through the top surface (14) of the reservoir (12). The therapeutic agent flows out of the aperture [Column 3, lines 39-46]. Finally, the two pieces of Parry's clip are considered to be detachably connected because they could be pulled apart.
19. Regarding Claim 15, the mating of the first projection with the second projection forces therapeutic agent to flow out of sponge in the reservoir and out of the aperture [Column 3, lines 39-46].
20. Regarding Claims 16 and 21, Parry discloses the invention as claimed, as detailed above. The clip attaches to the ear, which is made up of tissues including skin.

21. Claims 13, 16, and 18-21 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,282,829 to Hermes. Regarding Claim 13, Hermes discloses a surgical clip, as shown in Figure 1, with two pieces. The first piece (13) has a first base and a first projection extending from the first base [see Attachment #1]. The second piece (3&7) has a second base (3) and a second projection (7) extending from the base. The second projection includes multiple surfaces (interior), which define a reservoir. The surfaces include a surface towards the bottom of the cylindrical inner surface of the projection and side portions. Additionally, the second projection of Hermes' invention has a top surface, as described in Column 4 lines 13-14 [if the reservoir, i.e. "core" is completely enclosed, then the tip of the projection will necessarily be closed, although shown as open in Fig. 1]. The two pieces are detachably connectable. That is, because Hermes' two pieces are made of bioabsorbable material [Column 8, lines 54-55], when the clip (or part of the clip) degrades, the two pieces will disengage.

Further regarding Claim 13, the reservoir of Hermes' device contains a therapeutic agent, i.e. drugs [Column 4 line 61—Column 5 line 10].

Lastly, Hermes discloses a device having a second projection with apertures ["pores"] sized to allow the flow of the drug out of the reservoir. The pores of Hermes' device are throughout the device, so are therefore also located in the second projection [Column 5, lines 13-26].

22. Regarding Claim 16, Hermes discloses the invention, as described above with reference to Claim 13, and as further discussed below. Hermes' device is for

fastening body tissue, and would therefore be placed in proximity of the tissue [Column 1, lines 7-16]. Further, the therapeutic agent in Hermes' fastening device flows from the apertures in the second projection [Column 5, lines 19-26].

23. Regarding Claim 18, Hermes discloses a clip placed in proximity of a blood vessel [Column 1, lines 45-65]. In explaining the uses and applications for his invention, one of the intended uses is in blood vessels. His clip has the grooves (hollow portion 13) for accepting the shank of a piercing member [see Fig. 1], just like US Patent No. 3,918,455 that he references as being in a class of clips used to fasten blood vessels.
24. Regarding Claims 19, 20, and 21 Hermes discloses a clip for use with ligaments, tendons, and skin. Although he does not use these words specifically, he does say that his clip should be used to "fasten, secure, and/or repair *body tissue*" [Column 1, lines 7-13 and that it should function "to close incisions or wounds" [Column 3, lines 3-8]. Although incisions and wounds are generally thought of as happening to the *skin*, incisions and wounds happen in other body tissue as well, particularly in ligaments and tendons. In reference to fastening skin, Hermes cites U.S. Patent No. 4,994,073 to Green in his background art as one of the fields of use of his invention. Green's invention is a *skin fastener* having two pieces that are attachable [see Figures 1a and 1b].

With regards to fastening ligaments and tendons, although not referenced specifically by Hermes, U.S. Patent No. 6,120,526 to Daley shows that ligaments and tendons are understood to be included by the term "tissue" and that it is well known



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to fasten ligaments and tendons with two pieces that are attachable [Column 5, lines 24-28].

*Allowable Subject Matter*

25. Claims 10, 14, and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

*Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 4,994,073 to Green

U.S. Patent No. 6,120,526 to Daley

U.S. Patent No. 6,095,915 to Geissler et al.

U.S. Patent No. 4,871,542 to Vilhardt

U.S. Patent No. 4,961,931 to Wong

U.S. Patent No. 2,367,657 to Boersma

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on (703) 308-2496. The fax phone numbers for the

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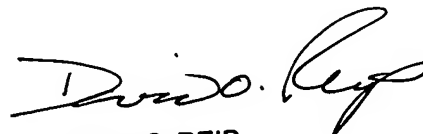
organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

*BCP*

BCP

July 17, 2003



DAVID O. REIP  
PRIMARY EXAMINER

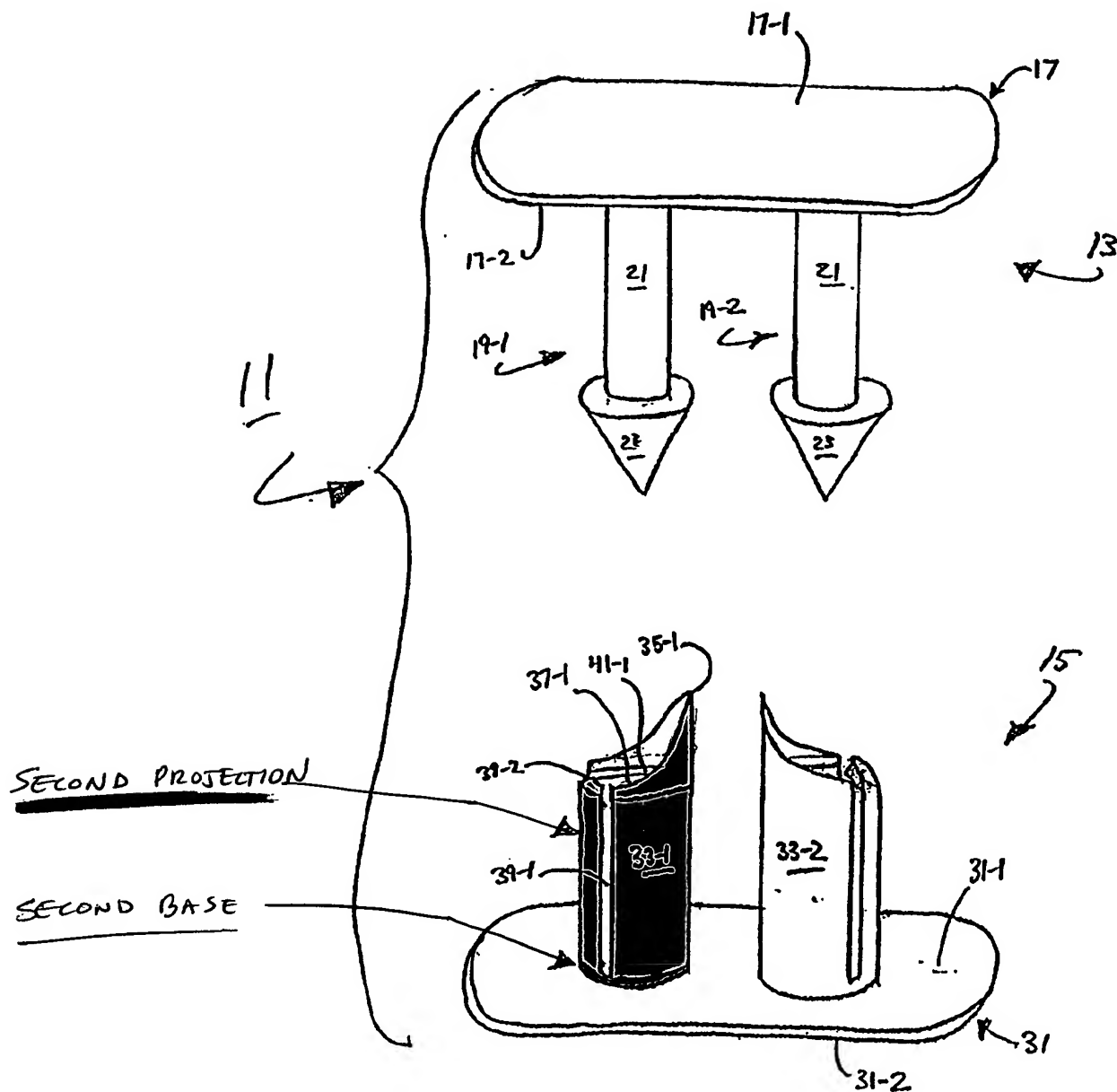


Fig. 2

